



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,321	07/28/2003	David Delaney	SKEL-007	6585
24353	7590	01/13/2006	EXAMINER	
BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303			JONES, DAMERON LEVEST	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 01/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/629,321	Applicant(s) DELANEY ET AL.	
	Examiner D. L. Jones	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10./25/05; 1/3/05; and 10/21/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
 4a) Of the above claim(s) 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 and 25-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/3/05 & 10/21/03.</u> | 6) <input type="checkbox"/> Other: _____ |

APPLICANT'S INVENTION

1. The instant invention is directed to a method of producing a flowable composition and kit thereof, a paste, and a package calcium phosphate cement as set forth in independent claims 1,15, 25, and 26.

Note: Claims 1-29 are pending.

RESPONSE TO APPLICANT'S ELECTION

2. Applicant's election with traverse of Group I (claims 1-23 and 25-29) filed 10/25/05 is acknowledged. The traversal is on the ground that a search of the entire scope of the instant invention would not be unduly burdensome on the Examiner. This is found non-persuasive because the inventions (Groups I and II) are distinct and require a separate search. For example, Group I is directed to a method of producing a composition that is a past/flowable/cement. However, Group II is directed to a method of repairing a hard tissue defect. Thus, prior art that anticipates or renders obvious a method of producing a composition would not necessarily render obvious or anticipate a method for repairing a hard tissue defect. Hence, a separate search of the art is necessary and is burdensome for the Examiner. Thus, the restriction requirement is still deemed proper and is therefore made FINAL.

WITHDRAWN CLAIMS

3. Claims 1 (as it relates to Group II) and 24 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

DOUBLE PATENTING REJECTIONS

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-23 and 25-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 and 14-18 of copending Application No. 10/851,766. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a setting fluid, dry reactants, and a contrast agent. The claims differ in that the instant invention is not limited to any particular contrast agent with 10/851,766 reads on a contrast agent that is a particulate of barium apatite. Thus, a skilled practitioner in the art would recognize that the instant invention encompasses the contrast agent of 10/851,766.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

112 REJECTIONS

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1: The claim as written is ambiguous because it is unclear what Applicant intends by the phrase 'that sets into' in line 1. Is Applicant saying that the flowable composition is 'incorporate within' a calcium phosphate containing product or that the

Art Unit: 1618

flowable composition solidifies into a calcium phosphate containing product? Please clarify.

Claim 10: The claim as written is ambiguous because it is unclear which components the disclosed range is directed to. The range involves two components while there are three components (a, b, and c) present in the composition.

102 REJECTIONS

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

9. Claims 1-7, 11, 14-17, 20, 22, and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Wenz (WO 2004/050131).

Art Unit: 1618

Wenz discloses a cement preparation that comprises a powdery component including calcium phosphate and an aqueous liquid component. A radio opaque material is added to at least one of the powder and liquid components, and the components may be combined into a pasty substance (see entire document, especially, abstract; page 6, paragraph [0018]). Another embodiment disclosed by Wenz is directed to a process for the preparation of a cement wherein the calcium phosphate, preferably an apatite material, powder is mixed with a contrast agent, and water or an aqueous component, and the mixture is allowed to harden (page 2, paragraph [0008]). The cement preparation comprises a mixture of salts. The contrast agent may be a barium salt, tantalum, zirconium, or tungsten (pages 2-3, bridging paragraph). In Example 1 (page 10), a cement composition is disclosed wherein components comprising tricalcium phosphate, $\text{Mg}_3(\text{PO}_4)_2$, MgHPO_4 , SrCO_3 , and BaSO_4 are thoroughly mixed with $(\text{NH}_4)_2\text{HPO}_4$ to generate a pasty mass which subsequently hardens. In Example 2 (page 10), all of the components of Example 1 with the exception of BaSO_4 were thoroughly mixed and allowed to harden. The compressive strength of the components was found to be 24.11 MPa. Thus, both Applicant and Wenz disclose a method of producing a flowable composition and a method of producing a paste composition wherein the composition comprises calcium and phosphate source, a setting fluid, and a contrast agent.

103 REJECTIONS

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1618

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1, 7-10, 13, 15, 18, 21, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wenz (WO 2004/050131) in view of Constantz et al (US Patent No. 6,334,891).

Wenz fails to disclose (see discussion above) a kit and packaged cement having a tubular element containing the components. In addition, Wenz does not specifically disclose that barium chloride is used or that the flowing composition sets in about 5 to 10 minutes.

Constantz et al disclose paste compositions that can be administered by syringe to set in situ to serve as a support structure, filler, or prosthesis (see entire document, especially, abstract). The reactants may comprise phosphate and calcium containing products and a liquid (columns 4-5, bridging paragraph). Implantation of the composition may be by syringe or catheter. The composition components once mixed are allowed to anneal while remaining quiescent, followed by an extended period of time during which the mixture hardens. During the hardening stage, crystal growth occurs and the product becomes an integral mass. Hardening will take at least about 5 minutes, usually, at least about 15 minutes, and not more than about 20 minutes (column 6, lines 19-33). In addition, the components of the composition may be packaged in kit form (column 11, claim 11).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Wenz using the teachings of Constantz et al and generate both a kit and packaged cement product because Constantz et al disclose that it is known in the art to place the components of a paste comprising a calcium source, phosphate source, and other necessary components into a kit (see claim 11, for example, in Constantz et al). In regards to the packaging of the of the cement and the use of a tubular element, Constantz et al not only disclose that the cement components may be placed in a kit, but also address how implantation of the composition occurs. Implantation may be by syringe or catheter wherein the composition may be used as a paste that is passed through a needle. Hence, the use of a tubular element is within the scope of Constantz et al. Furthermore, since both Wenz and Constantz et al disclose compositions comprising a calcium and a phosphate source, and a setting fluid, a skilled practitioner in the art would recognize that the references are within the same field of endeavor. Thus, the teachings of the references are combinable.

It would have been obvious to one of ordinary skill in the art at the time the invention was made that barium chloride is encompassed within the scope of the phrase 'barium salt' as set forth by Wenz. In addition, the skilled practitioner in the art would recognize that that the composition begins to set within 10 minutes because Wenz discloses that once the components are added and mixed thoroughly, the mixture subsequently hardens indicating that once all ingredients are present and mixed hardening begins instantly (see for example, Example 1, page 10). Furthermore, as

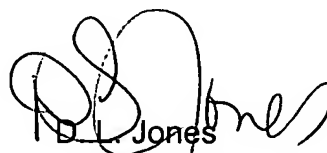
Art Unit: 1618

indicated in Constantz et al, hardening ranges from about 5 minutes to about 20 minutes which overlaps the range set forth by Applicant.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


D. L. Jones
Primary Examiner
Art Unit 1618

January 5, 2006